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TO AMEMBASSY NEW DELHI

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E.O.11652:NA

TAGS: TPHY OSCI TBIO IN

SUBJECT: DHEW/PHS/SFCP NEW PROPOSAL, "EPIDEMIOLOGICAL STUDIES
ON STOKES IN YOUNG"

REF: NEW DELHI 15634

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1. SUBJECT ICMR PROPOSAL WAS GIVEN PRELIMINARY REVIEWS BY
NATIONAL HEART LUNG INSTITUTE AND NATIONAL INSTITUTE NEUROLOGICAL
DISEASES STROKE. BOTH INSTITUTES HAVE HAD EXTENSIVE EXPERIENCE
WITH LARGE, LONG-TERM EPIDEMIOLOGY STUDIES AND THEIR PITFALLS.
THE DEFICIENCIES FOUND IN THE EXPERIMENTAL DESIGN OF SUBJECT
PROPOSAL ARE SUCH THAT IT CANNOT BE SUPPORTED IN ITS PRESENT
FORM. HOWEVER, NINDS, WHICH HAS PRIMARY RESPONSIBILITY FOR
STROKE RESEARCH, IS WILLING TO CONSIDER A REVISED PROPOSAL.
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2. THE PROPOSAL APPEARS TO SUFFER FROM HAVING BEEN WRITTEN
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CENTRALLY BY ICMR WITHOUT ADEQUATE DESIGN INPUT FROM TECHNICALLY

COMPETENT PARTICIPANTS. THIS WAS CONFIRMED TO SOME EXTENT BY DR. P.M. DALAL, BOMBAY, DURING HIS SEPTEMBER VISIT TO NIH. HE REPORTED THAT THE PROPOSAL HAD BEEN SENT TO HIM BY ICMR WITH A REQUEST THAT HE PARTICIPATE. ALTHOUGH HE NOTED SEVER DEFICIENCIES IN THE STUDY AND MADE RECOMMENDATIONS TO ICMR FOR IMPROVING THE DESIGN, HE RELUCTANTLY AGREED TO PARTICIPATE AS HE HAD NO ALTERNATIVE. HE HAD HEARD NOTHING FURTHER ABOUT THE PROPOSAL UNTIL HE SAW IT AT NIH AND FOUND HIS SUGGESTIONS HAD NOT BEEN INCLUDED. DALAL IS KNOWN TO NINDS AS A CAPABLE INVESTIGATOR WHO HAS MADE SOME UNIQUE FINDINGS IN INDIA RELATED TO STROKE. HIS COMMENTS SHOULD NOT BE REFERRED TO IN SUCH A WAY THAT HE CAN BE IDENTIFIED BY ICMR.

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3. SUMMARY OF REVIEWS FOLLOWS:

NHLI REVIEW: DETAILS OF THE STUDY DESIGN ARE INADEQUATELY SPECIFIED TO PERMIT COMPLETE EVALUATION OF THIS PROPOSAL; IT IS NOT CLEAR WHETHER PATIENTS WILL BE OBTAINED FROM HOSPITALS OR FROM A HOUSEHOLD SURVEY. NO DATA ARE PROVIDED REGARDING CRITERIA FOR HEART DISEASE, USE OF ECG'S, OR STANDARDIZED ANGINA QUESTIONNAIRES. THE STUDY IS SAID TO BE HOSPITAL-BASED AND TO HAVE A CASE-CONTROL DESIGN. NO INFORMATION IS GIVEN CONCERNING THE NUMBER OF CASES TO BE STUDIED, THE POPULATION OF REFERENCE, THE METHODS OF SELECTION, OR DIAGNOSTIC CRITERIA TO BE USED. CONTROLS ARE SAID TO BE MATCHED, BUT METHODS AND MATCHING CRITERIA ARE NOT GIVEN. NO CONSIDERATION IS GIVEN TO THE RELATIVE MERITS OF A MATCHED DESIGN FOR THIS STUDY. THE STATED PURPOSE OF THE STUDY -- TO DETERMINE PREVALENCE AND RISK FACTORS -- DOES NOT INDICATE THAT PARTICULAR HYPOTHESES ARE BEING ENTERTAINED OR THAT THE PRESENT STUDY IS UNIQUELY SUITED TO TEST THEM. A FORM FOR A FAMILY INTERVIEW IS ENCLOSED, BUT THERE IS NOT INFORMATION REGARDING A SURVEY. THE FORM IS IMPRECISE. FOR EXAMPLY, QUESTIONS ARE ASKED CONCERNING FAMILY HISTORY OF VARIOUS DISEASES WITHOUTH SPECIFYING WHICH RELATIVES ARE INCLUDED. OTHER FORMS ALSO APPEAR TO LACK DEFINITION. FOR EXAMPLE, A DIETARY FORM QUERIES THE FREQUENCY OF

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CONSUMPTION OF HYDROGENATED FAT WITHOUT INDICATING WHICH FOOD ITEMS WILL BE CONSIDERED BYDROGENATED. THERE IS NOT INFORMATION CONCERNING CHEMICAL DETERMINATION. WILL LABORATORY WORK BE CENTRALIZED? WHAT ARE THE PERFORMATNCE LEVELS WITH RESPECT TO ACCURACY AND PRECISION?

NIND REVIEW: AS PRESENTED, THE PROPOSAL LACKS SUFFICIENT INFORMATION TO INDICATE WHAT SUCH A STUDY WILL ADD TO OUR KNOWLEDGE.

NO HOSPITAL REGISTRY CAN EVER BE OFFERED AS A TRUE MEASURE OF THE PREVALENCE OF ANY DISORDER. THE VELLORE GROUP HAS SHOWN THAT COMMUNITY STUDIES ARE NECESSARY TO IDENTIFY THE SIGNIFICANT NUMBER OF YOUNG PEOPLE WITH STROKES WHO DO NOT PRESENT FOR MEDICAL CARE. THUS IT DOES NOT SEEM THAT THE PROPOSAL CAN ACHIEVE ITS FIRST OBJECTIVE, TO DETERMINE THE TRUE PREVALENCE OF STROKE IN THE YOUNG. THE EXTENSIVE INFORMATION OBTAINED ON EACH PATIENT WHO PRESENTS WITH STROKE IS CERTAINLY A PREREQUISITE TO A SEARCH FOR RISK FACTORS. THE AUTHORS DO NOT INCLUDE ANY HYPOTHESE THAT THEY WOULD LIKE TO TEST, NOT DO THEY DESCRIBE THE POPULATION THAT WILL SERVE AS A REFERENCE FOR THE EXPECTED FREQUENCIES OF ANY ABNORMALITY IN PEOPLE WHO DO NOT HAVE STROKE. IN ADDITION, THE AUTHORS DO NOT SUGGEST EVEN SIMPLE DESCRIPTIONS OF RISK FACTOR DISTRIBUTION IN SUBPOPULATIONS. NO MENTION IS MADE OF SAMPLE SIZE, ALTHOUGH IT IS STATED THAT FOUR CENTERS WILL BE PARTICIPATING FOR THREE YEARS. JUSTIFICATION FOR SUCH AN EXTENSIVE STUDY IS NEEDED.

ADDITIONAL INFORMATION IS NECESSARY TO JUSTIFY THE PRESENCE AT EACH CENTER OF SUCH A LARGE STAFF, YET CERTAIN NECESSARY EXPENSES HAVE NOT BEEN CONSIDERED: A SALARY FOR A PERSON TO OVERSEE THE ENTIRE PROJECT AND TRAVEL EXPENSES FOR MEMBERS OF THE PARTICIPATING CENTERS TO MEET FREQUENTLY TO DISCUSS MUTUAL PROBLEMS AND INSURE UNIFORMITY OF DATA COLLECTION. THIS TOPIC DESERVES STUDY, BUT THERE ARE MANY QUESTIONS TO BE ANSWERED BEFORE FINANCIAL SUPPORT CAN BE RECOMMENDED.

4. IT IS RECOMMENDED THAT THESE CRITIQUES BE TRANSMITTED TO ICMR WITH THE REQUEST THAT THEY PREPARE A REVISED PROPOSAL.

5. IT WILL BE NOTED THAT BOTH REVIEWS CITE THE LACK OF A HYPOTHESIS. THIS IS ONE OF THE MOST ELEMENTAL FEATURES OF A RESEARCH PROJECT DESCRIPTION AND ESSENTIAL TO ALL RESEARCH LIMITED OFFICIAL USE

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PROPOSALS SUBMITTED FOR REVIEW AND SUPPORT BY NIH.

6. SINCE THE ICMR PLANS TO DEVELOP RESEARCH PROPOSALS TO AN INCREASING EXTENT, IT IS BELIEVED ESSENTIAL THAT SCIATT GIVE IT AN ORIENTATION ON HOW TO WRITE RESEARCH PROPOSALS. BACKGROUND INFORMATION CAN BE PROVIDED BY NIH FOR THIS PURPOSE. THIS WOULD MAKE A SIGNIFICANT CONTRIBUTION TO IMPROVED PROPOSALS AND ENHANCE PROPOSAL ACCEPTANCE AND REALIZATION OF ICMR AND DHEW OBJECTIVES. KISSINGER

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